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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,619	12/05/2003	Heike Pahl	LEDER-0001-D01	7893

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/727,619	PAHL, HEIKE	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 9-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 4, 9-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 05 December 2003 has been entered in full. Claims 1, 4, 9, 11-12, 14-15, 17-18, 20-23 are amended. Claims 2-3 and 5-8 are cancelled. Claims 24-29 are added.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1, 4, 13, 15, 18, 21, 22, 24, 27, drawn to an isolated polypeptide of SEQ ID NO: 2, an isolated polynucleotide of SEQ ID NO: 1, process for detecting polycythaemia vera, classified in class 435, subclass 6, for example.

   II. Claims 11-12, drawn to a process for detecting polycythaemia vera characterized in that the polypeptide of SEQ ID NO: 2 is reacted with one or more antibodies, classified in class 435, subclass 7.1.

   III. Claim 9-10, 14, 23, 25-26, and 28-29, drawn to antibodies against the polypeptide of SEQ ID NO: 2 and a drug for treating polycythaemia vera characterized in that it comprises polyclonal or monoclonal antibodies, classified in class 424, subclass 130.1.

   IV. Claims 16 and 19, drawn to gene therapy compositions and methods, classified in class 514, subclass 44.

   V. Claims 17 and 20, drawn to a method of using the polypeptide of SEQ ID NO: 2 as a growth factor, classified in class 424, subclass 185.1.

The inventions are distinct, each from the other because of the following reasons:

   a. Inventions I and II, IV-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the polypeptide and polynucleotide of Group I can be used in

materially different methods, such as to generate antibodies, cell culture assays, or diagnostic assays.

Furthermore, the distinct steps and products require separate, distinct, and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups I and II, IV-V together.

b. Inventions I and III are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the polypeptide and polynucleotide of Group I and the antibody of Group III are structurally distinct molecules. Also, the protein of Group I can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group III can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. Furthermore, the distinct products require separate, distinct, and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups I and III together.

c. Inventions I-II, IV-V are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Groups I-II, IV-V are different methods requiring different method steps, wherein each is not required, one for another. For example, Group I requires search and consideration of detecting the PRV-polynucleotide using RT-

PCT or blotting, which is not required by the other inventions. Group II requires search and consideration of utilizing antibodies in an immunoassay to detect polycythaemia vera, which is not required by the other inventions. Group IV requires search and consideration of administration of the polynucleotide of SEQ ID NO: 1 to treat pancytopenias and pancytopathies in the bone marrow and circulation, which is not required by the other inventions. Group V requires search and consideration of using the polypeptide of SEQ ID NO: 2 as a growth factor to treat/multiply cells ex vivo or in vitro, which is not required by the other inventions. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I-II and IV-V are patentably distinct.
Furthermore, the distinct steps and products require separate, distinct, and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups I-II and IV-V together.

d. Inventions III and II, IV-V are unrelated because the product of Group III is not used or otherwise involved in the processes of Groups II, IV-V.

2. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification and different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
Art Unit 1647
17 April 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER